ENGINEERING ANALYSIS
PHARMAVITE EAST COAST MANUFACTURING FACILITY
(OPELIKA FACILITY)
LEE COUNTY
FACILITY No. 206-0046

On November 17, 2011, the above facility submitted an Air Permit application for a Greenfield site being proposed for Opelika, Alabama. The Opelika facility will be a pharmaceutical company similar to Pharmavite's existing sister facility located in San Fernando, California (San Fernando Facility), which manufactures Nature Made Vitamins. The Opelika Facility will manufacture dietary supplements and have a targeted production capacity similar to the San Fernando Facility.

OPERATIONS:

The Opelika Facility's operations will consist of several processes in the manufacturing of its dietary supplements to include: 1. Tablet Manufacturing, 2. Soft-gel Manufacturing, 3. Coating, 4. Packaging and 5. Support Areas. The San Fernando facility's historical information was used in the Opelika facility's Air Permit preparation.

This facility is scheduled to be completed during a three phase construction by 2015. The facility could possibility hire up to 300 employees once the construction is completed. Their planned normal operating schedule is 6,240 hours per year.

1. Tablet Manufacturing – Raw powder materials are received into the air conditioned warehouse and stored in pallet racks until needed. Partial containers of raw materials are pre weighed into labeled containers in the weight room. All material is then milled and sifted as required, and charged into a blender for mixing. The mixed product is discharged into super sacks for transfer to tablet presses for tableting. Dust collection is provided for all of the above activities. Blended materials are fed by gravity from the super sacks into the tableting presses and compressed into individual tablets. The Tablets area uses dust collectors as well as a central Spencer vacuum system for room and equipment dust cleaning. Finished tablets are then loaded into coaters, which are also connected to the dust collection system, where they are sprayed with a liquid coating and dried. Finished product is loaded into super sacks and transported to the packaging area. Tablets requiring inspection are transferred in super sacks to the inspection area for inspection via inspection belt or automated vision inspection equipment.

Dust collection is provided for the inspection belts. Dust and particulates collected in the tableting process are routed to twin Farr unit baghouses that control emissions.

2. Soft-gel Manufacturing - Soft gelatin capsules are manufactured in a batch process in which gelatin pellets are heated in a tank of water and cooked until the gelatin is the consistency of syrup. Steam is passed through a heat exchanger and heats the water. Air is removed from the process by vacuum pump. The gelatin liquid then flows by gravity into an encapsulation machine, which cools and extrudes the gelatin into flat sheets, then encapsulates the fill material through a set of rotary dies. The fill material, which is typically oil contained in a drum or tote, is pumped into the cavity and the gelatin capsule is then sealed by pressure.

3. When raw materials in powder form are added to the fill material, the powders are weighed in a manner similar to that as described for the tablets above. Powders are processed using stone mills, high shear mixers, and Del mixers. Dust collection controls emissions that might be emitted during the powder processing. Dust and particulates collected in the soft-gel process are routed to twin Farr unit baghouses that control emissions.

The gelatin capsules transfer into a series of tumble dryers, in which moisture is removed in a dehumidified room. Finished gels are inspected and moved to the packaging area. Gel tanks, drier baskets, and machine parts are cleaned in a large washing machine using hot water.

4. Coating – The tablets will be coated in the five proposed pan coaters and one continuous coater, and the soft-gels will be processed in another continuous coater. A coating solution is sprayed onto the tablets or capsules as they are being tumbled in the coaters. Tablets are coated with either a clear or colored aqueous base coating solution. The soft gelatin capsules are coated in a continuous opaque tumbler prior to being inspected for packaging. The tablet and softgel continuous coaters are equipped with a bag-house to control particulates. A total of seven baghouses for the coaters will be utilized and exhausted to the atmosphere in addition to the two Farr unit baghouses from the manufacturing operations.

5. Packaging - Tablets or Soft-gels are loaded into the tablet filler, which fills the correct amount of tablets into the bottles. Tablet fillers are connected to the dust collection system. The bottles are capped, labeled; shrink wrapped, and loaded into shipper cases. The cases are palletized, stretch wrapped, and moved into trucks for shipment.

6. Support Areas – Process steam and hot water are provided by three (Numbered 1, 2, and 3) 12.5 MMBtu/hr natural gas fired boilers, and two (numbered 1, and 2) industrial hot water heaters located throughout the facility as required.

Emergency service is provided by a diesel fired 1100-kw generator, which is also used to power an electric 200-hp fire pump engine.

EMISSIONS:

Emissions are expected to be generated from several of their processes as listed above. The anticipated sources of emissions include: 1. Particulates from material processing, 2. VOCs from soft-gel coating, and 3. Combustion by products from boilers and emergency equipment. Although tablets are coated, this process is not anticipated to be a source of VOCs since the aqueous coating materials contain organics with very low vapor pressures that would not volatilize but adhere to and dry on the tablet surface. The soft-gel manufacturing process is largely a negligible source of emissions. The Opelika Facility's soft-gel and tablet targeted production capacity by 2015 are 5.7 billion and 9.8 billion annually, respectively.

1. Particulate Matter (PM) – Two Farr bag-houses will be installed to control particulates from the process areas, with the exception of the coating process, and one bag-house will be in operation at a time. Each coater will be controlled by a dedicated bag-house. The main purpose of the coater bag-house is to baffle the flow of air through the coating process. Some emissions will be generated during the loading of the coaters; however, overall anticipated particulate

emissions from the coater bag-houses are anticipated to be minimal. The majority of particulates generated occur in the tableting manufacturing area with minor emissions from the soft-gel and coating areas.

All bag-houses have a designed removal efficiency of 99%. The San Fernando facility uses 0.304 lb/MMtablets as its factor to calculate their PM emissions. An engineering emission factor of 50% is applied to the Opelika facility factor for conservative purposes to obtain an emission rate of 0.457 lb/MMtablets.

Some hazardous air pollutants may be emitted from powder handling. The San Fernando Facility's power sifting process indicates that zinc, manganese, and copper, and their compounds, may be emitted as particulate matter. Based on the proposed Opelika Facility's operations their HAP emissions will be negligible.

2. Volatile Organic Compounds (VOC) – The soft-gel coating operations are responsible for the VOC emissions. The proposed coating process will use low vapor pressure VOC solvents i.e. propylene glycol and triethyl citrate. Short term and long term emissions for the coaters are estimated based on mass balances given the quantity of coating consumed and the composition of the coating materials. The data from the San Fernando Facility's continuous coater is used for the Opelika Facility's proposed soft-gel continuous coating operations. The Opelika Facility's tablet continuous coater and pan coaters operations for VOC emissions are considered negligible. This facility will have three (3) 10,000 gallon storage tanks in which two (2) are filled with glycerin and the other one filled with Soybean Oil. Due to the very low vapor pressures of these organic liquids, anticipated organic emissions from storage of the liquids are negligible.

3. Combustion Sources - Emissions from the natural gas boilers and water heaters are determined based on AP-42 factors for stationary external combustion sources, natural gas combustion (Chapter 1.4, 6//98). Potential emissions from the natural gas combustion sources are based on the boilers and heaters operating at capacity, 8760 hours per year. The emissions from the emergency generator are calculated based on federal standards for new non-road compression ignition engines. The actual and potential emissions are calculated based on the engine operating 500 hours per year. Emissions from the fire-pump are not anticipated since the engine is electric driven off the generator.

Greenhouse Gases (GHG) – The potential GHG emissions from this facility's three (3) boilers (12.5 MMBtu/hr each), and two (2) heaters (1.5 MMBtu/hr each) are 21,336.51 tpy of CO_{2e} . Based on an annual usage of 500 hours the emergency generator's potential GHG emissions (CO_{2e}) is 423.93 tpy. Opelika Facility is not a major source for GHG.

	PM	PM 10/2.5	VOC	NOx	CO	SO2	HAP	HAPs	CO2e
Lb/hr	1.5	1.5	1.33	17.65	11.82	3.05	0.07	0.09	6,470 tpy
Actual tpy	4.68	4.68	4.12	55.07	36.88	9.52	0.22	0.28	8,556.6
Potential tpy	6.6	6.6	5.8	77.3	51.8	13.4	0.31	0.39	21,336.51

Actual and potential are based on 6,240 and 8,760 hr/yr, respectively.

REQUIREMENTS:

This facility is located in an attainment area for all pollutants. Based on their potential emissions, this facility is not subject to a PSD review.

1. The manufacturing of dietary supplements will be subject to **ADEM's Rule 335-3-4-.04** Process Industries for the control of particulate emissions, and **335-3-5-.01** Control of Sulfur compound Emissions from their fuel combustion operations.

(a) The Opelika Facility is located in a Class 1 County for Particulate Matter (PM). Based on $E = 3.59P^{0.62}$ when P<30 tons/hr, and $E = 17.31P^{0.16}$ when $P \geq 30$ tons/hr this facility allowable PM emissions shall be 76 tons/yr.

Where E = Emissions in pounds per hour, P = Process weight per hour in tons per hour.

(b) The Opelika Facility is located in a Category II County for Sulfur Dioxide (SO2) – No person shall cause or permit the operation of a fuel burning installation in a Sulfur Dioxide Category II County in such a manner that sulfur oxides, measured as sulfur dioxide, are emitted in excess of 4.0 pounds per million BTU heat input. This SO2 standard applies to the boilers and heaters. This standard should be attained through combustion of natural gas. The standard should not apply to the emergency generator since it is not intended for indirect heating.

2. This facility is subject to New Source Performance Standards (NSPS) **Subpart A for General Provisions**.

3. This facility is subject to **NSPS Subpart Dc** – standards of Performance for small Industrial Commercial Institutional Steam Generating Units. Each steam generating unit for which construction, modification, or reconstruction is commenced after June 9, 1989, and that has a maximum design heat input capacity of 29 MW (100 MMBtu/hr) or less, but greater than or equal to 2.9 MW (10 MMBtu/hr). Opelika Facility proposes to operate three (3) boilers rated at 12.5 MMBtu/hr.

4. This facility proposes to install a diesel fired 1,475-hp (1100-KW) emergency generator which will be subject to **NSPS Subpart IIII** – Standards of Performance for Stationary Compression Ignition Internal Combustion Engines. NSPS Subpart IIII applies to manufacturers, owners, and operators of stationary compression ignition (CI) internal combustion engines (ICE) manufactured after April 1, 2006,

(a) The generator engine would be required to meet the new nonroad CI engines requirements in 40 CFR 60.4202, specifically 60.4202(a)(2).

(b) According to the emissions standards under this section, the engine would be required to meet the requirements for new and in use nonroad compression ignition engines in 40 CFR 89.112 and 89.113.

The proposed fire pump engine will operate off of the generator and will not contribute additional emissions.

RECOMMENDATIONS:

This facility is considered a true minor for their emissions for PSD and Title V. Based on the Opelika Facility's Air Permit application I recommend issuing two (2) Air Permits: X001 – Vitamin Manufacturing, and X002 – Combustion Sources: 3 – 12.5 MMBtu/hr natural gas fired boilers, and 1 – 1475 hp emergency generator pending their application fees and a public notice period are received and completed, respectively.

_____ December 28, 2011

Clarence Fairer III Date
Chemical Branch
Air Division